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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,978	11/15/2006	Martin Pruschy	4-32911A	3436

1095 7590 06/16/2009

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
06/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,978	PRUSCHY, MARTIN	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *4/15/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The response filed on **4/15/09** has been entered.

2. Applicant's arguments filed 4/15/09 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-5 and 10 are pending in this office action. Claims 6-9 have been cancelled.

5. The objection to the numbering of claims as not in accordance with 37 CFR 1.126 is withdrawn due to Applicants renumbering of the claims.

6. The rejection of claim 8 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, is withdrawn due to the cancellation of the claim by the Applicant.

7. The rejection of claim 8 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn due to the cancellation of this claim.

8. Claim 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn due to the amendment of the claim.

9. Claims 1-5 and 10 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a solid tumor such as prostate, glioma and thyroid tumors as specified in the specification (page 2) with ionizing radiation, does not reasonably provide enablement for treating a wide variation of solid tumors in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons made of record in Paper No. 20090415 and as follows.

Applicant argues that the limitation "solid tumor" previously in claim 10 has been incorporated into the base claim, and therefore the rejection should be moot.

In response generically treating solid tumors is very broad and one cannot reasonably use a single drug to treat a vast variety of solid tumors, as previously made of record. Each particular solid tumor has its own specific characteristics and etiology. The unpredictability observed with single agent therapy is compounded when a

combination of agents is employed. The broad recitation of "treating solid tumor" is inclusive of many conditions that presently have no established successful therapies.

The art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy as already discussed in the last office action.

Applicant's arguments have been fully considered but they are not persuasive for the reasons given above and already made of record.

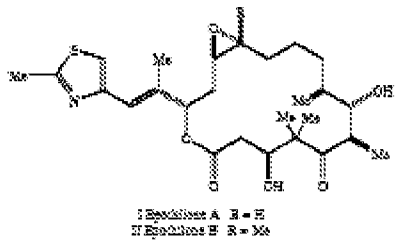
The Examiner suggests incorporating limitations such as treating prostate, glioma and thyroid tumors as specified in the specification (page 2) into instant claim 1 may obviate this rejection, as indicated in the scope of enablement section of the rejection, and as previously made of record.

10. Claim 10 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using epithilone derivatives of formula I, does not reasonably provide enablement for using prodrug esters thereof for the reasons made of record in Paper No. 20090415 and as follows.

No remarks or traversal was made by Applicant to the above rejection. Therefore the rejection is maintained as already made of record in the last office action.

11. Claims 1-5 and 11 stand rejected under 35 U.S.C. 102(e) as being anticipated by Vite et al. (US 6,605,599) for the reasons made of record in Paper No. 20090415 and as follows.

Applicant argues that "Vite et al is concerned with compounds defined by the formula disclosed from column 1, line 38, to column 2, line 54, (formula V); and that epothilones A and B are disclosed as the prior art. It is also clear that the disclosure at column 6, line 18-41, relates to potential combination therapies that include "compounds of the invention" and an additional therapeutic agent, and does not relate to combinations with the compounds defined as in present claims 2 and 3. Therefore, Vite et al does not even suggest the inventions defined by present claims 2 and 3, which are limited to combinations of radiation and compounds that are clearly excluded from the scope of Vite et al's generic formula V.

In response, Vite et al. teach the compound of the instant claims 1- 3, wherein the compound is an epothilone  wherein A is O, R is hydrogen or lower alkyl and Z is O (see specifically Example 7; col. 43, lines 40-55) is in a pharmaceutically acceptable salt in combination with radiation see col. 1, lines 14-30 and col. 6, line 20. Please note that both forms epothilone A and B are disclosed therein. Vite further teaches the compounds of formula I may be administered to humans with solid tumors such as ovary; colon, pancreas, lung and kidney (see col. 5, lines 23-67).

Administering the drug in combination with an ionization agent to therapeutically treat solid tumors is considered anticipated as required by instant claims 4-5 (see col. 6, line 18-20) because radiation used in the art is ionizing radiation.

The argument that formula V is excluded from the limitations recited in claims 2 and 3 is found not persuasive because the substituents of A in base claim 1 is O; as is W in Vite's compounds (see Example 7; col. 43, lines 40-55); and where R is a lower alkyl as also taught as R in Vite's example.

Unexpected Results

12. Applicant's argue teachings within "B. Hofstetter et al, Clinical Cancer Research, Vol. 11, 1588-1596 (2005) and C. Bley et al, Clinical cancer Research, Vol. 15(4), 1335-1342 (2009), that the 2005 article provides evidence of a multilayered synergistic response on cellular and tumor tissue levels induced by the combination of radiation and patupilone (aka epothilone B) and that the 2009 article discusses experiments determining the mechanism of combined epothilone B/radiation treatment".

In contrast, it should be noted that Vite et al. (US 6,605,599) is a statutory bar under 35 U.S.C. **102(b)**.

13. Claim 10 stands rejected under 35 U.S.C. 102(e) as being anticipated by Bandyopadhay et al. (WO 02/058699) for the reasons made of record in Paper No. 20090415 and as follows.

Applicant argues that "Bandyopadhay et al. does not disclose or suggest a kit which includes an instruction to use the epothilone in combination with ionization".

In response Bandyopadhay et al. discloses the compounds of epothilone A and B (see page 1, lines 21-24 are placed in a kit see page 6).

Bandyopadhay et al disclose the compounds of epothilone A and B see page 1, lines 21-24 are placed in a kit see page 6 and may be combined with know anticancer treatments such as radiation (see page 18, lines 7-8). It is considered that instruction of how to use it, is within the kit and thus anticipatory.

See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, its is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of Patentability is concerned. Also see MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art.

Applicant's arguments have been fully considered but they are not persuasive for the reasons already of record.

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
6/10/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649